

EXHIBIT D



DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

NEW ENGLAND DISTRICT
MEMORANDUM

Date: March 6, 2013

From: Karen Archdeacon, CO, NWE-DO

Subject: (b) (6)

To: Central File - Bard / Davol

On 3/6/13, I received a call from a (b) (6) (b) (6) C.R. Bard. He was calling NWE-DO after noting that our office issued a Warning Letter to Davol (division of CR Bard) in April 24, 2007. He stated that he was aware of problems with Bard's vena cava filters, labeled as G2 Filters. (Bard's website). He noted that this product was manufactured by Bard from 2004 – 2008.

(b) (7)(C)

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events (1000), that have not been reported to the FDA. (b) (7)(C)

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(b) (7)(C) FDA issued an advisory in August 9, 2010 that related to vena cava filters. (8.9.10 Advisory). He explained that the information recently obtained during the (b) (7)(C) that the firm was aware of a number of problems with the device, specifically complaints regarding breakages, migrations and perforations that have resulted in serious injuries. (b) (7)(C)

Bard's defense was that that since they were not able to collect all of the required information, (b) (7)(C) After seeing our 2007 Warning Letter, he noted this appears to a recurring problem at Bard.

I did state that I would forward the information to the appropriate FDA district offices for this particular company / product. I confirmed that the vena cava filter, the G2 was manufactured in Tempe AZ and the firm's corporate HQ remained in Murray Hill, NJ. (b) (7)(C) stated we could reach him at the above numbers, (b) (7)(C)

The telecom was then concluded.

NWE-DO Memo of Telecom
Bard

3/6/13

Page 2 of 2

Karen E.
Archdeacon

Digitally signed by Karen E. Archdeacon
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300053369,
cn=Karen E. Archdeacon
Date: 2013.03.06 14:42:05 -05'00'

Karen Archdeacon
Compliance Officer
New England District Office

Cc (hard copy): CF (1213643 Davol,), KNA, S. VanTwuyver, CDRH – B. MacFarland,
DAL-DO, NWJ-DO, C. Zuckerman

Cc (electronic): KNA h file